

## **AMENDMENTS TO THE CLAIMS:**

Please add new claims 112-124 as follows. A complete listing of the claims with proper claim identifiers follows.

### **Listing of Claims**

1. (Previously presented) A fluid handling device having a housing, a sealing surface and a flow control member comprising a flexible material biased against said sealing surface, characterized in that the flow control member is overmolded onto a constructive member of the fluid handling device such that they can be handled as one unit when being assembled with the housing to produce the fluid handling device.
2. (Previously presented) The fluid handling device of claim 1 wherein the device is suitable for transferring medical fluids.
3. (Previously presented) The fluid handling device of claim 1 wherein the fluid handling device comprises a needlefree access device.
4. (Previously presented) A fluid handling device comprising:
  - a) a housing having an inlet and an outlet and comprising a first housing part and a second housing part;
  - b) a sealing surface inside the housing; and
  - c) a sealing member comprising a flexible material biased against the sealing surface;
  - d) wherein the first and second housing parts are produced from thermoplastic material, and the sealing member and the second housing part are molded together such that they can be handled as one unit when being assembled with the first housing part to produce the fluid handling device.
5. (Previously presented) The fluid handling device of claim 4 wherein the device is suitable for handling medical fluids.

6. (Previously presented) The fluid handling device of claim 4 wherein the first housing part comprises said inlet and the second housing part comprises said outlet.

7. (Previously presented) The fluid handling device of claim 4 wherein the fluid handling device comprises a check valve.

8. (Previously presented) The fluid handling device of claim 4 wherein the fluid handling device comprises a luer activated valve.

9. (Previously presented) A method of making a fluid handling device comprising:

a) forming a first housing part from a thermoplastic material, the first housing part having a sealing surface;

b) forming a second housing part from a thermoplastic material;

c) forming a sealing member comprising a flexible material by overmolding the sealing member to the second housing part such that the second housing member and sealing member can be handled as one unit when being assembled with the first housing part; and

d) connecting the first housing member and second housing member together, with the sealing member biased against the sealing surface, to form the fluid handling device.

10. (Previously presented) The method of claim 9 wherein the flexible material comprises a thermosetting material.

11. (Previously presented) The method of claim 9 wherein the first and the second housing members are connected by ultrasonic welding.

12. (Previously presented) A fluid handling device according to claim 1, characterized in that the fluid handling device is a needlefree access device.

13. (Previously presented) A needlefree access device comprising:

- a) a housing having an inlet and an inlet channel; and
- b) a combination outlet, biasing and piston member having
  - i) a piston section moveable between a closed position in which the piston section is in the inlet channel and an open position in which the piston section is inside the housing below the inlet channel but allows fluid to flow through the inlet channel,
  - ii) a biasing section connected to the piston section that normally biases the piston section into the inlet channel; and
  - iii) an outlet section interlocked to the biasing section and having an outlet fitting in fluid communication with the inside of the housing; wherein the piston section, biasing section and outlet section are connected together such that they can be handled as one piece when assembled with the housing to make the needlefree access device.

14. (Previously presented) The needlefree access device of claim 13 wherein the inlet channel comprises a female luer taper.

15. (Previously presented) The needlefree access device of claim 13 wherein the piston section in its closed position seals the inlet channel against airborne bacteria.

16. (Previously presented) The needlefree access device of claim 13 wherein the combination outlet, biasing and piston member comprises thermoplastic material and resilient material.

17. (Previously presented) The needlefree access device of claim 16 wherein the resilient material is overmolded onto the thermoplastic material.

18. (Previously presented) The needlefree access device of claim 13 wherein the piston section in its closed position is either flush with or extends out of the housing inlet.

19. (Previously presented) The needlefree access device of claim 13 wherein the biasing section is made from resilient material.

20. (Previously presented) The needlefree access device of claim 19 wherein the resilient material of the biasing section has a Shore A durometer of between about 30 and 90.

21. (Previously presented) The needlefree access device of claim 13 wherein the biasing section has a solid central section.

22. (Previously presented) The needlefree access device of claim 16 wherein the resilient material is a resilient thermosetting material.

23. (Previously presented) The needlefree access device of claim 13 wherein the biasing section is generally hollow.

24. (Previously presented) The needlefree access device of claim 13 wherein the biasing section has a helical flow channel around its center portion.

25. (Previously presented) The needlefree access device of claim 24 wherein the helical flow channel has a cross-sectional width of about 0.02 inches when the piston section is in its open position

26. (Previously presented) The needlefree access device of claim 24 wherein the helical flow channel has a cross-sectional width of about 0.04 inches when the piston section is in its open position.

27. (Previously presented) The needlefree access device of claim 13 wherein the piston section comprises a normally elliptical top portion with a wedge shaped opening therein.

28. (Previously presented) The needlefree access device of claim 27 wherein the housing inlet is round and the piston member is deformable such that when the piston section is in its closed position, the top portion is forced into a round shape and the wedge shaped opening is closed.

29. (Previously presented) The needlefree access device of claim 28 wherein the piston section further comprises a radial flow channel beneath the wedge shaped opening.

30. (Previously presented) The needlefree access device of claim 13 wherein the housing comprises a generally smooth cylindrical wall surrounding the biasing section.

31. (Previously presented) The needlefree access device of claim 30 wherein the housing further comprises an internal threaded section adjacent the connection between the biasing section and the outlet section.

32. (Previously presented) The needlefree access device of claim 13 wherein the outlet section forms a closure to the housing, thus directing flow through the housing to pass through the outlet fitting.

33. (Previously presented) The needlefree access device of claim 32 wherein the outlet section has a flange sonically welded to a recess within the housing to form said closure.

34. (Previously presented) The needlefree access device of claim 19 wherein the resilient material of the biasing section has a Shore A durometer of between about 50 and about 80.

35. (Previously presented) The needlefree access device of claim 13 where in the piston section includes a wiper seal.

36. (Previously presented) The needlefree access device of claim 13 wherein the piston section and biasing section are formed as one monolithic piece.

37. (Previously presented) The needlefree access device of claim 36 wherein the monolithic piece is overmolded onto the outlet section to provide the combination outlet, biasing and piston member.

38. (Previously presented) A fluid handling device comprising:  
a) a housing; and  
b) a flow control member, the flow control member comprising thermoplastic material and resilient thermosetting material overmolded onto the thermoplastic material.

39. (Previously presented) The fluid handling device of claim 38 wherein the flow control member is made in a two-shot molding process.

40. (Previously presented) The fluid handling device of claim 38 comprising a needlefree access device.

41. (Previously presented) The needlefree access device of claim 40 wherein the flow control member comprises a piston section, a biasing section and an outlet section, the piston and biasing section being made from the resilient thermosetting material and the outlet section being made from the thermoplastic material.

42. (Previously presented) The needlefree access device of claim 41 wherein the housing comprises an inlet channel and the biasing section normally biases the piston section to close the inlet channel.

43. (Previously presented) The needlefree access device of claim 42 wherein the biasing section provides a force of between about 0.2 lbs and about 3.5 lbs.

44. (Previously presented) The fluid handling device of claim 38 comprising a check valve and wherein the flow control member comprises a diaphragm.

45. (Previously presented) A flow control member for use in a fluid transfer device, the flow control member comprising:

- a) a housing part formed of thermoplastic material; and
- b) a sealing member overmolded onto the housing part.

46. (Previously presented) The flow control member of claim 45 for use with a needlefree access device wherein the flow control member comprises a combined biasing section and piston section formed from resilient material, and the housing part comprises an outlet section.

47. (Previously presented) The flow control member of claim 45 wherein the resilient material comprises thermosetting material.

48. (Previously presented) The flow control member of claim 47 wherein the thermosetting material comprises silicone.

49. (Previously presented) The flow control member of claim 45 wherein the resilient material comprises thermoplastic elastomer.

50. (Previously presented) The flow control member of claim 46 wherein the biasing section has a solid central portion and is shaped in a helix.

51. (Previously presented) The flow control member of claim 46 wherein the biasing section has a central hollow portion and a helical flow channel formed in its outer surface.

52. (Previously presented) The flow control member of claim 46 wherein the piston section comprises a normally elliptical top portion with a wedge shaped opening therein.

53. (Previously presented) The flow control member of claim 46 wherein the piston section comprises an opening in the top thereof; and a flow channel beneath and connected to the opening and extending radially to the outside of the piston section, the flow channel having a cross-sectional area larger than that of the opening in the top of the piston.

54. (Previously presented) The flow control member of claim 46 wherein the piston section comprises a normally elliptical top portion with a V-shaped opening across a minor axis of the ellipse.

55. (Previously presented) The flow control member of claim 46 wherein the outlet section is mechanical interlocked to the biasing section.

56. (Previously presented) A needlefree access device comprising:  
a) a housing having a round inlet, a tapered inlet channel that narrows inwardly from the inlet, a main body portion and a base opposite the inlet;

b) a piston member inside the housing; and  
c) a biasing member inside the housing normally biasing the piston member to close the inlet;  
d) wherein the piston member comprises a resilient material with a top having a generally elliptical shape and an opening that is closed when the top of the piston is forced into said round inlet opening but which allows flow through the opening to the outside of the piston member when the piston member is forced downwardly against the biasing force and out of the tapered inlet channel.

57. (Previously presented) The needlefree access device of claim 56 wherein the opening in the piston member is wedge-shaped.

58. (Previously presented) The needlefree access device of claim 56 wherein the opening comprises an opening in the top surface of the piston member and a flow channel underneath the opening in the top which is wider in cross-section than the opening in the top.

59. (Previously presented) The needlefree access device of claim 56 wherein the biasing member comprises a resilient member formed monolithically with the piston member.

60. (Previously presented) The needlefree access device of claim 59 wherein the biasing member has a hollow central portion, but the opening in the piston does not interconnect with the hollow central portion.



61. (Previously presented) The needlefree access device of claim 56 wherein the piston member includes a wiper seal capable of preventing airborne bacterial ingress while the piston is in a closed position.

62. (Previously presented) The needlefree access device of claim 45 wherein the wiper seal can also withstand a pressure of at least 2 psi.

63. (Previously presented) The needlefree access device of claim 56 wherein the piston has a top surface that extends above the inlet.

64. (Previously presented) The needlefree access device of claim 63 wherein the top surface of the piston member is slanted and extends above the inlet on only one side of the access device.

65. (Previously presented) The needlefree access device of claim 57 wherein the wedge shaped opening extends radially to one side of the piston member from a point which is between the centerline of the piston member and the opposite side of the piston member.

66. (Previously presented) A method of making a needlefree access device comprising:

- a) forming a housing having an inlet and a base;
- b) forming a flow control member by
  - i) molding thermoplastic material to form an outlet member and
  - ii) overmolding resilient material onto the outlet member, the resilient material forming a piston section and a biasing section;
- c) inserting the flow control member into the housing such that the piston section is adjacent to the inlet; and
- d) securing the outlet member into the base of the housing.

67. (Previously presented) The method of claim 66 wherein the outlet member is sonically welded into the base of the housing.

68. (Previously presented) The method of claim 66 wherein the thermoplastic material is injected in a molten state into a mold having a base section and a first top section and allowed to solidify.

69. (Previously presented) The method of claim 68 wherein after the thermoplastic material is allowed to solidify, the first top section of the mold is removed, the solidified thermoplastic material remains in the base section of the mold and a second top section mold is placed over the base section of the mold, the second top section having a cavity for molding the resilient material.

70. (Previously presented) The method of claim 69 wherein the resilient material is a silicone thermosetting material made by mixing silicone part A and silicone part B together and injecting the mixture into the cavity in the second top section.

71. (Previously presented) The method of claim 70 wherein the mixture is injected at a pressure of between about 100 psi and about 900 psi, and at a temperature of between about 50°F and about 100°F.

72. (Previously presented) The method of claim 68 wherein the thermoplastic material is injected at a temperature of between about 300°F and about 800°F, and at a pressure of between about 500 psi and about 2000 psi.

73. (Previously presented) The method of claim 70 wherein the second top mold section is at a temperature of between about 250°F and about 400°F when the mixture is injected.

74. (Previously presented) The method of claim 68 wherein the mold base section is at a temperature of between about 50°F and about 300°F when the thermoplastic material is injected.

75. (Previously presented) The method of claim 66 wherein the thermoplastic material is selected from the group consisting of polycarbonates, polysulfones, nylons and acrylics.

76. (Previously presented) A method of making a needlefree access device comprising:
- a) providing a first part comprising a monolithically formed housing;
  - b) providing a second part comprising a combination outlet section, biasing section and piston section;
  - c) constructing the needlefree access device by securing the second part within the first part, the access device being made only from the first and second parts.
77. (Previously presented) A needlefree access device comprising:
- a) a housing; and
  - b) a flow control member, the flow control member comprising a thermoplastic outlet section and a resilient material overmolded onto the thermoplastic material.
78. (Previously presented) The needlefree access device of claim 77 wherein the housing includes threads for a luer lock fitting in the area surrounding the inlet channel.
79. (Previously presented) The needlefree access device of claim 77 wherein the housing comprises a base with threads for forming a luer lock.
80. (Previously presented) The needlefree access device of claim 13 wherein the housing comprises an internal sealing surface and the piston section seals against the sealing surface to prevent backflow through the access device when the piston section is in its closed position.
81. (Previously presented) The needlefree access device of claim 35 wherein the wiper seal closes the inlet against airborne bacteria when the piston section is in the closed position.
82. (Previously presented) A needlefree access device comprising:

- a) a housing having an inlet, a base, and a main body portion having a generally cylindrical inside surface between the inlet and the base;
- b) a valve member actuatable between an open position and a closed position, wherein in the closed position the valve member prevents flow between the inlet and the outlet;
- c) a central body within the main body portion of the housing, the central body having a helical shape on its outer surface, the central body fitting against the inside of the cylindrical surface when the valve member is in its open position;
- d) the helical shape defining a helical flow path through the main body portion of the housing when the valve member is in an open position.

83. (Previously presented) The needlefree access device of claim 82 wherein the housing further comprises a tapered inlet channel having a luer taper for engaging with a syringe tip having a luer taper.

84. (Previously presented) The needlefree access device of claim 82 wherein the valve member is formed as part of a piston section of a combined piston section and biasing section.

85. (Previously presented) The needlefree access device of claim 84 wherein the central body forms part of the biasing section.

86. (Previously presented) The needlefree access device of claim 84 wherein the combined piston and biasing section comprises resilient material and is overmolded onto an outlet section comprising thermoplastic material, which in turn is attached to the base of the housing.

87. (Previously presented) The flow control member of claim 46 wherein the top portion of the piston has a V-shaped opening therein.

88. (Previously presented) The needlefree access device of claim 59 wherein the biasing member has a solid central portion.

89. (Previously presented) The needlefree access device of claim 13 wherein the needlefree access device is in the form of a Y-shape access device, and comprises a secondary inlet.

90. (Previously presented) The needlefree access device of claim 89 wherein the secondary inlet is formed in the housing.

91. (Previously presented) The needlefree access device of claim 89 wherein the secondary inlet is formed in the outlet section.

92. (Previously presented) An IV bag having a port comprising a needlefree access device as recited in claim 13.

93. (Previously presented) A needlefree access device comprising:
- a) a housing having an inlet, an inlet channel and an outlet; and
  - b) a biasing and piston member having
    - i) a piston section moveable between a closed position in which the piston section is in the inlet channel and an open position in which the piston section is inside the housing below the inlet channel but allows fluid to flow through the inlet channel; and
    - ii) a biasing section connected to the piston section that normally biases the piston section into the inlet channel, the biasing section comprising a resilient body having a helical shape on at least part of its outer surface.

94. (Previously presented) The needlefree access device of claim 93 wherein the helical shape comprises at least one complete helical revolution.

95. (Previously presented) The needlefree access device of claim 93 wherein the helical shape comprises less than one complete helical revolution.

96. (Previously presented) The needlefree access device of claim 93 wherein the housing is made of a housing member and an outlet member secured to the housing member and providing the outlet thereof.

97. (Previously presented) The needlefree access device of claim 96 wherein the outlet member comprises an outlet section interlocked to the biasing section and having an outlet fitting in fluid communication with the inside of the housing; wherein the piston section, biasing section and outlet section are connected together such that they can be handled as one piece when assembled with the housing to make the needlefree access device.

98. (Previously presented) A check valve having a first and a second housing part and a flexible sealing member positioned therebetween, which is adjacent a sealing surface such that overpressure in an entry space of the first housing part causes the sealing member to be lifted from the sealing surface, opening a flow path through the check valve, wherein the two housings parts are produced from thermoplastic material by injection molding, and wherein the sealing member and the second housing part are molded together such that they can be handled as one unit when assembled with the first housing part for producing the check valve.

99. (Previously presented) The check valve of claim 98 wherein the sealing member is pretensioned against the sealing surface.

100. (Previously presented) The check valve of claim 98 having a T-shaped housing with two inlets and one outlet, wherein the first inlet is positioned coaxially to the outlet and the second inlet is controlled by the check valve.

101. (Previously presented) The check valve of claim 98 wherein the connection between the first inlet and the outlet is by way of a valve chamber which is closed by a cover positioned opposite to the second inlet, the cover comprising the second housing part.

102. (Previously presented) The check valve of claim 98 wherein the sealing member comprises a resilient thermosetting material.

103. (Previously presented) The check valve of claim 98 wherein the sealing member comprises silicon.

104. (Previously presented) The check valve of claim 98 wherein the second housing part and connected sealing member are formed by a two-shot injection molding process.

105. (Previously presented) The check valve of claim 98 wherein the first housing part comprises a female luer-lock-connector.

106. (Previously presented) The check of claim 98 wherein the second housing part comprises a male luer-lock-connector.

107. (Previously presented) A method for producing a check valve comprising the steps of:

- a) injection molding a housing part from a thermoplastic material having an inlet and an annular sealing surface within an entry space;
- b) injection molding a second housing part from a thermoplastic material;
- c) overmolding an elastic material onto the second housing part, the elastic material forming a sealing member;
- d) inserting the second housing part and the sealing member into the first housing part in such a way that the sealing member is pretensioned against the annular sealing surface; and
- e) connecting the first and the second housing parts.

108. (Previously presented) The method of claim 107 wherein the first and the second housing parts are connected by ultrasonic welding.

109. (Previously presented) The method of claim 107 wherein the second housing part is not removed from the mold prior to the overmolding step, and at least part of the mold used in the overmolding step was used in the step of injection molding the second housing part.

110. (Previously presented) A check valve comprising:

- a) a housing having an inlet and an outlet and comprising, a first housing part and a second housing part;

- b) a sealing surface inside the housing; and
- c) a sealing member comprising a flexible material adjacent the sealing surface;
- d) wherein the first and second housing parts are produced from a thermoplastic material by injection molding, and the sealing member and the second housing part are molded together such that they can be handled as one unit when being assembled with the first housing part for producing the check valve.

111. (Previously presented) The check valve of claim 110 having a T-shaped injection molded housing of thermoplastic material with two inlets and one outlet, wherein flow through the second inlet is controlled by the sealing member, and wherein the connection between the first inlet and the outlet is by way of a valve chamber which is closed by a cover positioned opposite to the second inlet, the cover comprising said second housing part and being connected together with the flexible material.

112. (New) A needlefree access device comprising:

- a) a housing having a round inlet, an inlet channel, a main body portion and a base opposite the inlet;
- b) a piston member inside the housing; and
- c) a biasing member inside the housing normally biasing the piston member to close the inlet;
- d) wherein the piston member comprises a resilient material with a top having an opening that is closed when the top of the piston is in said round inlet opening but which allows flow through the opening to the outside of the piston member when the piston member is forced downwardly against the biasing force and out of the inlet channel.

113. (New) The needlefree access device of claim 112 wherein the piston is formed by a molding operation, and the opening is molded into the piston member when it is formed.



114. (New) The needlefree access device of claim 112 wherein the inlet channel is tapered, narrowing inwardly from the inlet.

115. (New) A needlefree access device in an open state comprising:

- a) a housing having an inlet, an outlet and a fluid channel therethrough;
- b) a piston in the fluid channel, downstream of the inlet, the piston comprising a top, a side and an opening, the opening extending from the top into the piston and opening to the side of the piston, the opening being shaped and positioned such that fluid entering the housing inlet may flow through the opening from the top of the piston and outwardly into the fluid channel in the housing.

116. (New) A needlefree access device comprising:

- a) a housing having an inlet, an outlet and a fluid channel, and;
- b) a flow control member inside the fluid channel interacting with the housing to close the fluid channel and prevent flow of fluid when the device is in a closed state, and to provide a fluid flow path through the device when the device is in an open state;
- c) wherein the housing is clear and a user has visual access through the clear housing to see the flow path.

117. (New) The needlefree access device of claim 116 wherein the fluid flow channel comprises an inlet channel and an enlarged section, and the flow control member comprises a piston with a head having an opening therein, the piston head being in the inlet channel with the opening closed when the device is in a closed state, and the piston being pushed inwardly to where the enlarged section allows the opening to open when the device is in an open state.

118. (New) A needlefree access device comprising:

- a) a housing having an inlet and a fluid flow channel;

b) a base outlet section connected to the housing and having an outlet and a transverse fluid flow channel in fluid communication with the outlet; and

c) a flexible biasing and piston member on top of the base outlet section and extending into the housing, the biasing and piston member including a top section fitting in the housing inlet and having a top surface and a side surface, the top section comprising a wiper seal to seal the inlet when the device is in a closed state and an opening that extends from the top surface to the side surface of the top section of the piston and allows fluid introduced into the inlet when the device is in an open state to pass through the opening to the outlet in the base outlet section.

119. (New) The needlefree access device of claim 118 wherein the biasing and piston member comprises an air chamber, and wherein the base outlet section further comprises at least one vent channel, and the air chamber is vented through the at least one vent channel in the base.

120. (New) The needlefree access device of claim 119 wherein the base section comprises multiple vent channels and the top side of the base outlet section includes a relief cut into it that connects the vent channels, which prevents the biasing and piston member from blocking the vent channels when the biasing and piston member is compressed.

121. (New) The needlefree access device of claim 119 wherein the housing has one or more flow channels formed in a side wall of the housing such that when the piston member is pushed down, the air chamber collapses, with air flowing out of the at least one vent channel, and fluid introduced in the inlet may flow through the one or more flow channels in the side wall of the housing, past the biasing and piston member, to the transverse fluid flow channel in the base outlet section.

122. (New) A method of making a needlefree access device comprising:

- a) forming a housing having a round inlet opening, an inlet channel and a base;
- b) forming an outlet member;
- c) forming a flow control member comprising a piston member and a biasing member;
- d) inserting the flow control member into the housing such that the piston member is adjacent to the inlet, the piston member comprising a resilient material with a top having an opening that is closed when the top of the piston is in said round inlet opening but which allows flow through the opening to the outside of the piston member when the piston member is forced downwardly against the biasing member and out of the inlet channel; and
- e) securing the outlet member to the base of the housing.

123. (New) The method of claim 122 wherein the piston member is formed by a molding operation, and the opening is molded into the piston member when it is formed.

124. (New) The method of claim 122 wherein the piston member and biasing member are part of one monolithic structure.